

REMARKS

I. Introduction

The Office Action mailed December 11, 2008, has been carefully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of the Claims

Claims 1, 7-10, 12, and 16-18 are pending. Claims 2-6, 11, and 13-15 have been cancelled. Claims 1, 9-10, and 16-18 have been amended. Support for the amendment to claim 1 is found, inter alia, in original claim 5 and in the specification, table on page 7 (showing the molar ratio of rabeprazole to alkaline compound of about 1:0359). Claims 9 and 16 have been amended to be consistent with claim 1 and to delete “the.” Claims 10 and 17 have been amended to delete “the.” Claim 18 has been amended as suggested by the Examiner and to be consistent with the amendment to claim 1. Support for this amendment is the same as that for the amendment to claim 1.

III. Summary of the Office Action

In the Office Action, the Examiner objects to the claims because of informalities. Particularly, the Examiner objects to

- 1) claims 9, 10, 16, and 17 because “...the said...” is redundant; and
- 2) claim 18 because “[t]he words ‘Water For Injection’ and ‘Mannitol’ should not be capitalized” and because “the word ‘lounging’ should be ‘bunging.’”

The Examiner also rejects

- 1) claim 1, 6, 9, 10, 6, and 17 under 35 U.S.C. § 102(a) as being anticipated by Doen et al. (U.S. Patent Application Publication No. 2003/0191157);
- 2) claims 1-5, 7, 8, 12, 15, and 18 35 U.S.C. § 103(a) as being obvious over Doen et al.

IV. Arguments

Applicant respectfully traverses the rejections for the following reasons:

A. The claims are proper

Claims 9, 10, 16, and 17 stand objected to because “...the said...” is redundant.

Applicants have amended those claims to delete the word “the.”

Claim 18 stand objected to because “[t]he words ‘Water For Injection’ and ‘Mannitol’ should not be capitalized” and because “the word ‘lounging’ should be ‘bunging.’” Applicants have amended those claims as suggested by the Examiner.

Therefore, Applicants respectfully submit that the claims are now proper. Accordingly, withdrawal of the rejection is earnestly solicited.

B. The claims are not anticipated Doen et al.

Claim 1, 6, 9, 10, 6, and 17 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Doen et al. Applicants respectfully traverse the rejection.

Doen et al. fail to disclose every limitation of the claimed invention. In particular, Doen et al. fail to disclose that “the molar ratio of rabeprazole sodium to the alkaline compounds is about 1:0.359” as recited in independent claim 1. In paragraph [0096] of Doen et al., the molar

ratio used is 1:0.9 to 1:1.1. This is much higher than the ratio of 1:0.359. Therefore, Doen et al. cannot anticipate the present invention within the meaning of 35 U.S.C. § 102. Accordingly, Applicants respectfully request withdrawal of the rejection.

C. The claims are not anticipated by Doen et al.

Claims 1-5, 7, 8, 12, 15, and 18 stand rejected under 35 U.S.C. § 103 as being obvious over Doen et al. Applicants respectfully traverse the rejection.

The deficiency of Doen et al. is discussed above. Applicants respectfully submit that there is no rationale to modify the teaching of Doen et al. to increase the ratio of rabeprazole to alkaline compound to 1:0.359. Doen et al. specifically disclose a compound containing benzimidazole, such as rabeprazole, and “a strong alkali in molar ration of about 1:1.” *See* paragraph [0010]. Subsequently, Doen et al. discloses that the ratio may be about 1:0.90 to 1:1.10. *See* paragraph [0022]. The formulation of Doen et al. is designed to overcome the problems of prior art as follows:

The inventors of the present invention did intensive research, and finally found that such an injectable composition that there is no need to attach the exclusive dissolving solution for the injectable composition and that the kneading operation and the complicated dissolving operation are not required can be obtained by using a 2-[*(2-pyridyl)methylsulfinyl*]benzimidazole compound having an antiulcer action and a strong alkali in molar ratio of about 1:1.

Paragraph [0010]. Thus, the 1:1 ratio is a critical component of Doen et al.’s invention. This ratio contains over 2.5 times the amount of an alkali than that of the present invention. One of ordinary skill in the art would have no rationale to modify this ratio to arrive at the present invention because to do so would render Doen et al. “unsatisfactory of its intended purposes.” See MPEP 2143.01(V) (“The proposed modification cannot render the prior art unsatisfactory

for its intended purpose.”). Here, Doen et al. have discovered a critical ratio to resolve certain problems in the art (the problems are discussed in paragraphs [0003] to [0006]). Thus, one of ordinary skill in the art would not have any rationale to disturb this critical ratio. Doen et al. clearly teach against doing so by stressing the criticality of their benzimidazole to strong alkali ratio. Changing this ratio would eviscerate the function and teaching of Doen et al. Therefore, because one of ordinary skill in the art would have no rationale to modify the ratio of Doen et al. to arrive at the present invention, the reference cannot render the present invention obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Conclusion

Applicants have responded to the Office Action mailed December 11, 2008. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (125139.0101). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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